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CFF 10463867 Revision 02
Only the Native File to be Used

SEP 26 2007

510(k) Summary of Safety and Effectiveness

Submitter's Name/Contact Person

Amarilys Machado
Manager, Regulatory Affairs

Cordis Neurovascular, Inc.
14000 NW 57th Court
Miami Lakes, Florida 33014

Ph. 786 313 6493
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Trade Name / Common Name

The trade name is :
Vascular Occlusion System (TRUFILL® Pushable Coils and TRUPUSH® Coil Pusher)

The common name is:
Artificial Embolization Device

Classification

This is a Class II Device, per 21 CFR 882.5950 (84HCG)

Performance Standard

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this device.

Intended use

The intended use of the TRUFILL® Vascular Occlusion System (TRUFILL® Pushable Coils and TRUPUSH® Coil Pusher) is as follows:

Pushable Coils may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Device Description

The TRUPUSH® Coil Pusher is used in coil embolization procedures in both the neuro and peripheral vascular systems. An embolic coil is loaded into the proximal end of a compatible microcatheter and the Coil Pusher is used to advance the device through the catheter lumen until it has exited the distal tip of the catheter.

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Predicate Devices The predicate devices are listed in the table below:

Device	Company	Product Code	510(k) Number	Predicate for: (if multiple predicates)
TRUPUSH® Coil Pusher	Cordis Neurovascular, Inc.	K983483	HCG	- Intended Use - Design - Operating Principle - Materials - Sterilization - Shelf Life - Manufacturing Process

Summary of Studies

The *in-vitro* and *in-vivo* testing was conducted to support substantial equivalence to the predicate device, addressing the process changes, packaging changes and manufacturing site transfer.

Design Verification Testing:

- Total Product Length
- Taper Length
- OD of the Proximal Joint
- OD of the Distal Joint
- OD of the Proximal End of the PTFE Sleeve
- Proximal Marker Position
- Distal Placement of the PTFE Sleeve
- PTFE Sleeve Visual Inspection
- Distal End of PTFE Sleeve Visual Inspection
- Overall Visual Inspection
- Distance from the Proximal End of the PTFE Sleeve to the Corewire Taper
- Distal Solder Joint Length
- Distal Solder Joint Visuals
- Turns to Failure
- Distal Joint Strength
- Package Integrity
- Package Challenge
- Seal Integrity Test (Dye Penetration)
- Packaging-Seal Strength (Pull Test)
- Product Migration

Design Validation Testing:

- 3-cavity torque device clip
- Pushability
- Retractability

Summary of Substantial Equivalence

The proposed TRUPUSH® Coil Pusher is similar in its basic design, construction, indication for use, and performance characteristics to the predicate device the current TRUPUSH® Coil Pusher.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cordis Neurovascular, Inc.
% Amarilys Machado
Regulatory Affairs Manager
14000 Northwest, 57th Court
Miami Lakes, Florida 33014

SEP 26 2007

Re: K071962
Trade/Device Name: Vascular Occlusion System (TRUFILL® Pushable Coils and TRUPUSH® Coil Pusher)
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: August 27, 2007
Received: August 28, 2007

Dear Amarilys Machado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071962

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Indications for Use

510(k) Number (if known):

Device Name: TRUPUSH® Coil Pusher

Indications For Use:

The intended use of the TRUFILL® Vascular Occlusion System (TRUFILL® Pushable Coils and TRUPUSH® Coil Pusher) is as follows:

Pushable Coils may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

K071962

510(k) Number

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)